Docket: 2005D-0169 - Draft Guidance - Components of Useful Written Consumer Medication Information (CMI)

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General Remarks

The US has until now been more cautious than Europe and Australasia in imposing regulation on CMI. Arguably, this has led to the US being behind other countries in the provision of useful CMI (viz the research of Bonnie Svarstad's team), with an unsatisfactory level of provision, and a unacceptably high proportion of poor quality leaflets. However, this now puts the US in a position of advantage, in being able to observe the effect of the regulation in Europe and Australasia, and learn from this experience, before implementation. My comments here draw on current research into CMI provision in the 3 continents, funded by the DIA[1].

Australia (with collaboration from New Zealand) adopted a highly multi-disciplinary approach in the 1990s to the development of a CMI policy. This included significant input from patients and academics. The result was leaflets which are useful to patients, as demonstrated by performance-based User Testing of the leaflets (required to be undertaken by companies before a licence is granted by the authorities).

However, the resulting leaflets took some time to become widely available to patients, because these electronically based leaflets were to be printed out in pharmacies on demand. The delay was due to the lack of remuneration of pharmacists to fund the printers and consumables needed. Another downside is that the leaflets can be long – up to 3 or 4 sides of A4 paper. This was due to the inability to include high level formatting of the information – just a 3 column format with no colour or other design features. The lessons are:

- ✓ Include meaningful input of patient representatives in developing policy on consumer medicines information
- ✓ Include meanignful input of researchers with expertise in consumer medicines information
- ✓ Ensure the infra-structure for the delivery of the CMI to the patient is in place, with appropriate resourcing
- ✓ Pay attention to capabilities of the printers used to produce electronically generated leaflets

In **Europe**, legislation was enacted in 1999, making comprehensive manufacturers' leaflets (delivered as package inserts) mandatory. The guidance on the content and

[1] "Consumer medicines information in US, Europe and Australia - A comparative evaluation". Researchers: Theo Raynor, Peter Knapp, Parisa Aslani & Ines Krass (Sydney), Bonnie Svarstad (Wisconsin, USA). Funder: Drug Information Association

layout of these leaflets was in some ways at variance with good practice in information design. This led to problems such as:

- The inclusion of manufacturer' details (including addresses) and a full list of excipients near the top of the leaflet – this was universally disliked by patients [2] (this aspect of the regulations has now been changed)
- The suggestion that words like "very common", "common", "rare" should be used to express the frequency of side effects – research subsequently showed that this led to patients grossly over-estimating the risk of side effects occuring. [3]
- Proposed use of wordings "Immediately" and "As soon as possible" which in practice people do not distinguish between[4]
- Consumers do not like the package insert method of delivery – it makes the multiply folded, thin paper leaflet harder to read[5,6].

The lessons are:

- ✓ Consult with patient organisations before adopting policy
- ✓ Ensure that experts in CMI and information design have input
- ✓ Test wordings before recommending their use
- ✓ Do not use the package insert route of delivery.

My final general comment is that both Australasia and Europe now require manufacturers' leaflets to be tested on the target patient population, to ensure that people can both find and understand the key points of information. Such performance based testing should be considered in the US.

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[2] Dickinson D, Raynor DK, Duman M. Patient information leaflets for medicines: using consumer testing to determine the most effective design. Patient Education and Counseling 2001; 43: 147-159.

[3] Knapp P, Raynor DK, Berry DC. Comparison of two methods of presenting risk information to patients about the side effects of medicines. Quality and Safety in Healthcare 2004; 13: 176-180

[4] Berry D, Raynor DK, Knapp P. Over the counter medicines and the need for immediate action: a further evaluation of European Commission recommended wordings for communicating risk. Patient Education and Counselling 2004; 53: 129-134.

[5] Raynor DK, Savage I, Knapp P, Henley J. We are the experts. People with asthma talk about their medicine information needs. Patient Education and Counselling 2004; 53: 167-174.

[6] Raynor DK,Knapp P. Do patients see read & retain the new mandatory medicines information leaflets? Pharmaceutical Journal 2000;264:268-270

Specific Remarks

A. GENERAL CONSIDERATIONS

CMI that adheres to the Action Plan criteria for a specific prescription drug will be considered *useful* when:

(1) the most recent FDA-approved professional labeling or package insert (PI) serves as the source document for the information contained in CMI

- **This (and other clauses) will dramatically increase the size of most current US leaflets. Although welcome, the implications of this need to be thought through before implementation.**

(2) it includes the components suggested in the Action Plan and substantially conforms to the formatting suggestions made in the Action Plan.

B. Specific Recommendations for Each Action Plan Criterion

Criterion 1: Drug Name, Indications for Use, and How to Monitor for Improvement

- Established name and brand name (e.g., the trademark or proprietary name) of the drug and the phonetic spelling (pronunciation) of the established name. FDA recommends also including the phonetic spelling of the brand name.
- All FDA-approved indications listed in the PI for the medication. Information on unapproved indications should only be included in CMI customized for individual patients
  - **The absence of information on "off-label" indications on CMI is a frequent source of complaint by patients in the UK. This is a welcome proposal.**

Criterion 2: Contraindications and What to Do if They Apply

- Directions about what to do if any of the contraindications apply to the patient, such as contacting the healthcare provider before taking the medicine or discussing with him or her situations that would warrant discontinuing use of the medication. Include a general statement such as, *Talk to your healthcare provider before taking this medicine if you have any of these conditions*
  - **I welcome the use of indicative statements like this, rather than statutory wordings. This will allow innovation.**

Criterion 3: Specific Directions About How to Use and Store the Medicine and Information About Overdose

- A statement should be included in the CMI to stress the importance of adhering to the dosing instructions prescribed by the healthcare provider.
  - **The wording of such a statement needs to be considered carefully. One of the objectives of useful CMI is that people taking medicines should be able to make balanced decisions about whether the medicine is right for them.**

Criterion 4: Specific Precautions and Warnings

- Any risks to the mother and the fetus or the infant from use of the drug during pregnancy, labor, or breast-feeding. If the risks are unknown, include a statement such as, *Talk to your doctor if you are pregnant or breast-feeding. It is not known if the medicine will affect your baby*.

    - **We tend in the UK not to include refreshingly honest statements such as this, which acknowledge uncertainty. It is to be welcomed.**

Criterion 5: Symptoms of Serious or Frequent Possible Adverse Reactions and What to Do

- The most serious potential adverse reactions will most likely appear in the w*arnings* or *Precautions* sections of the PI; we recommend that this information be included in CMI. In addition, we recommend that CMI include a list of, at minimum, the symptoms of at least the 5 to 9 most frequently occurring (common) adverse reactions.

    - **This is proposal is vague and open to different interpretations. It would mean that:**
        - **Different leaflets for the same preparation could vary widely (as writers interpret the "5 to 9" in different ways)**
        - **Drugs vary widely in the number of known side-effects (at a rough estimate 10 – 30), so " 5 to 9" would include almost all the side effects for one drug but less than a third for others.**

    Specifying a proportion of the common side effects to list eg 50% would be preferable. However, is such an approach sustainable? Who is to decide which side effects a patient should not be told about. I suggest that patient input into this policy decision is essential.

Criterion 6: Certain General Information, Including Encouraging Patients to Communicate with Healthcare Professionals, and Disclaimers

- A statement encouraging discussion with a healthcare professional about the prescription medicine. A statement that the healthcare professional who prescribed the medicine has additional information about the medicine as well as about the patient's specific health needs, and that the healthcare professional can provide this information to the patient and answer the patient's questions. An example of a statement that covers both recommendations could be: *This leaflet summarizes the most important information about <insert medication name>. If you would like more information, talk with your doctor*.
    - **or pharmacist?**

Criterion 7: Information That Is Scientifically Accurate, Unbiased in Tone and Content, and Up-to-Date

- Scientific accuracy is an essential characteristic of CMI. The entire CMI will be assessed for scientific accuracy and bias.

- The information in the CMI should be consistent with or derived from the PI, unless the CMI is customized for individual patients.

Criterion 8: Information in an Understandable and Legible Format That Is Readily Comprehensible to Consumers

- To be useful, CMI should be written in wording that is understandable. To meet the Action Plan criterion of being understandable, we suggest that CMI be provided at the sixth to eighth grade reading level.

- This can be achieved by using a validated readability instrument. We encourage using plain language and looking at the message from the reader's point of view.

    - **Is reference to school grade reading level and readability instruments still useful? Readability Formulae are largely discredited by many academics in this field. If the instrument is based on word and sentence length (as most are) then the text written backwards will have the same "score" as when written forwards. The only way to determine if a leaflet is "useful" is to undertake performance based testing.**

- We recommend that CMI be designed to ensure the prominence of important information. It is helpful to use formats that distinguish between the degree of seriousness of cautions or warnings.

    - **This will only be useful guidance if it includes some suggestions as how this can be done effectively.**

- Information should be written clearly and concisely, and complex terms should be avoided. Polysyllabic words could be replaced by shorter, simpler words (e.g., *harmful* rather than *detrimental*), even if it takes several words to get across a concept that can be expressed in a single, more complex term.

We recommend the following formatting:

- Use 10-point or larger type size.

    - **This is smaller than the proposed new UK guidance which recomments 12 point type size (the size recommended by the Royal National Institute for the Blind). However, the use of 10 point is more realistic, provided that an appropriate type face is used**

- Do not use ornate typefaces and italics.

    - **I note that italics are used in this guidance document**

  Choose a bolder type over a thin version of the same style.
- Use upper- and lower-case lettering, not all capitals.
- Use bold-face type or a box to call attention to important information, rather than highlighting or underlining.

    - **There is evidence that information contained in closed boxes can lead to information being skipped over.**

- Provide adequate space between letters, lines, and paragraphs. We suggest that text generally have no more than –3 *kerning* (space between letters). With 10-point type, 12-point *leading* (space between lines) is recommended (at least 2.2 millimeters). Provide adequate space between paragraphs and space above and below headings.
- Do not use a line length that is too long. In 10-point or 12-point type, optimal line length is approximately 40 letters long.

- Select text color and paper that give a strong contrast. Black, dark blue, or brown ink on white or pale yellow uncoated paper provides the best contrast. We suggest that other combinations be avoided.
- Use short paragraphs and bullets where possible.
    - **I suggest this should be "always", rather that "where possible" . It is also worth noting that if bullets are used too frequently or with more than 9 in one list, then they tend to lose their effectiveness.**

C. Summary

The components of useful information identified in the Action Plan are meant to be useful "as a total package." We suggest that the information be provided in the following order:

1. Personalized information in a box (if customized for individual patients)
2. Established name and brand name
3. What the medicine is used for
4. Do not take this medicine if you are…
5. How to take the medicine
6. Side effects include …
7. General information
    - **This is similar to the UK/EU sequence which seems to meet general acceptance**

This list is not the only appropriate headings or order in which the headings should appear. Moreover, information pertaining to each Action Plan criterion need not be organized under the above-specified individual headings; they can be combined as appropriate.

DK Theo Raynor 22 July 2005